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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/774,708	02/09/2004	Kenneth Beaman	112461-021	9549	
43793	7590 05/11/200	5	EXAMINER		
	INTELLECTUAL P	SKELDING, ZACHARY S			
	P. O. BOX 708 NORTHBROOK, IL 60065		ART UNIT	PAPER NUMBER	
			1644		

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		Application No.	Applicant(s)	<del></del>
		10/774,708	BEAMAN, KENNET	ГН
Office Action Summary		Examiner	Art Unit	
		Zachary Skelding	1644	
Period fo	The MAILING DATE of this communication app	ears on the cover sheet w	rith the correspondence add	lress
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL' CHEVER IS LONGER, FROM THE MAILING Downsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNI 36(a). In no event, however, may a will apply and will expire SIX (6) MO , cause the application to become A	CATION. reply be timely filed  NTHS from the mailing date of this cor BANDONED (35 U.S.C. § 133).	,
Status	,			
2a)⊠	Responsive to communication(s) filed on <u>03 M</u> This action is <b>FINAL</b> . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final.		merits is
Dispositi	ion of Claims			
5)□ 6)⊠ 7)⊠	Claim(s) 1,6-33 and 35-122 is/are pending in the same claim(s) 7-14,17-33 and 36-13 Claim(s) is/are allowed.  Claim(s) 1,6,15,16 and 35 is/are rejected.  Claim(s) 16 is/are objected to.  Claim(s) are subject to restriction and/or	22 is/are withdrawn from	consideration.	•
Applicati	ion Papers			
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b)  objected to drawing(s) be held in abeyation is required if the drawing	nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFF	
Priority u	ınder 35 U.S.C. § 119			
a)[	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureausee the attached detailed Office action for a list	s have been received. s have been received in A ity documents have beer I (PCT Rule 17.2(a)).	Application No  received in this National S	Stage
Attachmen	t(s)			
2)	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	Paper No(	Summary (PTO-413) s)/Mail Date nformal Patent Application (PTO- 	152)

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## **DETAILED ACTION**

1. Applicant's amendment filed March 3, 2006 has been entered.

Claims 1, 6-33, and 35-122 are pending.

Claims 2-5 and 34 have been canceled.

Claims 7-14, 17-33 and 36-122 are withdrawn.

Claims 1, 6, 15, 16 and 35 have been amended.

2. This Office Action is in response to Applicants amendments and remarks filed March 3, 2006.

The rejections of record can be found in the previous Office Action, mailed November 29, 2005.

The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior action.

3. The previous objections have been withdrawn in view of applicant's amendments. The previous rejection under 35 U.S.C. § 112, 2nd paragraph has been withdrawn in view of applicant's amendments.

Upon reconsideration, and in view of applicant's amendments, the previous rejection under 35 U.S.C. § 112, 1st paragraph, written description has been withdrawn.

4. Claim 6 is objected to because of the lack of singular/plural agreement between the singular "wherein the antibod<u>y</u>..." and the plural "monoclonal antibod<u>ies</u> and polyclonal antibod<u>ies</u>".

Applicant is invited to amend the claim to recite, "wherein the antibody is a monoclonal antibody or a polyclonal antibody."

5. Claims 1, 6, 15 and 35 are rejected under 35 U.S.C. § 112, 1st paragraph, because the specification does not provide a sufficient enabling description of a method of inducing secretion of interleukin- $1\beta$  (IL- $1\beta$ ) in *any* mammalian or human cell.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant asserts that Example 13 supports the use of anti-RTF antibody to cause apoptosis in ovarian carcinoma cells. Applicant further asserts, "...other cell types could be targeted without departing from the scope of the present invention."

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Applicant's argument is not found persuasive because, while the instant specification enables a method comprising the administration of anti-RTF antibody wherein the administration leads to apoptosis of ovarian cancer cells, the instant specification does not sufficiently enable the use of the claimed methods with *any mammalian or human cell*. For example, Boomer et al. (Hum Immunol. 2000 Oct;61(10):959-71, provided with the previous Office Action) teaches that anti-RTF antibody does not induce apoptosis in unstimulated Jurkat human leukemia T cell line (see page 962, column 1, Anti-RTF antibody induces apoptosis; and page 966, Figure 4, in particular). Applicant has not provided sufficient objective guidance to support assertions of broad applicability to *any mammalian or human cell*. The method is unpredictable because not all cancer cells undergo apoptosis. Therefore, one of skill in the art would be required to perform undue experimentation in order to practice the claimed method, other than a method comprising the administration of anti-RTF antibody wherein the administration leads to apoptosis of ovarian cancer cells.

Thus, Applicant's arguments have not been found persuasive.

6. Claim 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for "killing of cancer cells".

Applicant's amendment, filed March 3, 2006, does not provide sufficient direction for the written description for the above-mentioned "limitation". While the instant application provides written description support for a method comprising the administration of anti-RTF antibody wherein the administration leads to apoptosis of ovarian cancer cells, the Examiner is unable to locate the written support for "killing of cancer cells".

The specification as filed does not provide a sufficient written description of "killing of cancer cells". The specification does not provide blazemarks nor direction for the instant methods encompassing "killing of cancer cells". This limitation, which was not clearly disclosed in the specification as-filed, changes the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to point out where the instant specification provides sufficient written support for "killing of cancer cells". See MPEP 714.02 and 2163.06

7. No claim is allowed. However, claim 16 is objected to as being dependent upon a rejected base claim, and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zachary S. Skelding, Ph.D. Patent Examiner 5/8/06

PHILLIP GAMBEL, PH.D JO PRIMARY EXAMINER